

## REMARKS

In the February 2, 1999, Office Action, the Examiner rejected all pending claims (claims 1-21). The Examiner indicated allowable subject matter in the elected claims and Applicant has incorporated the Examiner's suggestions to clarify the claimed subject matter. Through the amendments and remarks contained herein, the Applicant through undersigned counsel respectfully requests that the claims be allowed.

The rejections will be addressed in the order presented by the Examiner.

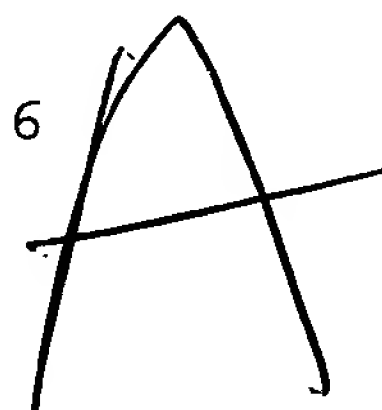
### *Drawings*

The Official Draftsman objected to the drawings. Formal drawings will be filed at a later time, prior to issue.

### *Claim Rejections--35 U.S.C. § 112*

The Examiner rejected claims 1-21 under 35 U.S.C. §112, second paragraph, because the phrase "operatively associated" in the base independent claim was vague. Claim 1 has been amended and the phrase removed. As rewritten, claim 1 now describes the positioning of the layers in relation to the upper support and lower support as interposed therein. The basis for this amendment can be found on page 6, lines 13-32, and Figure 1 of the specification.

6



***Claim Rejections--35 U.S.C. §102***

Through the above amendment, Claim 1 and all of its depending claims now contain elements and limitations previously determined by the Examiner not to be disclosed by Krause et al. The Examiner rejected claims 1 and 4 under 35 U.S.C. §102(b) as being anticipated by Krause et al. The Examiner also stated that the limitations in dependent claim 2 would be allowable if rewritten in independent form. Claim 1 is hereby amended to clarify the allowable limitations of claim 2. It is respectfully submitted that Krause is not an anticipatory reference in view of the claimed subject matter.

***Claim Rejections--35 U.S.C. §103***

Because the previously-described amendments to base independent claim 1 describe a device that is not obvious over Krause et al. in view of Allen et al., claims 5-9 and 15-19, which depend on claim 1, should no longer be rejected under 35 U.S.C. §103. The Examiner rejected claims 5-9 and 15-19 all of which depend on Claim 1. Claim 1 has been amended to clarify the elements of claim 2 which the Examiner has already determined to contain allowable subject matter. Therefore, the rejection regarding claims 5-9 and 15-19 has been overcome by the amendment to the base claim, claim 1, as the dependent claims are likewise allowable.

### ***Allowable Subject Matter***

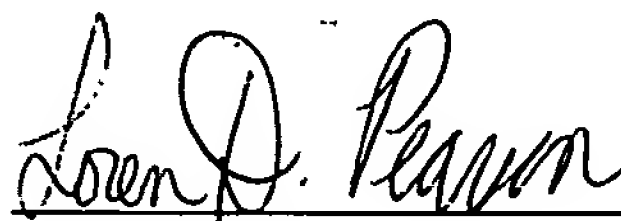
Added independent claims 22 and 24 (and dependent claim 23 that depends on claim 22) should be allowed because they are merely rewritten claims based on previously allowed subject matter. In the February 2, 1999, Office Action, the Examiner indicated that the subject matter of claims 2-3, 10-14, and 20-21, was allowable if rewritten in independent form. Claim 22 recites the material of originally filed claim 20 as an independent claim. Claim 24 recites the material of originally filed claim 14 as an independent claim.

### ***Conclusions***

In light of the above amendments, the undersigned attorney respectfully submits that the instant case is in condition for allowance, and respectfully requests favorable action. The Examiner is urged to telephone the undersigned attorney in order to expedite prosecution of the application at (954) 763-3303.

The Commissioner is hereby authorized to charge and missing or insufficient funds to Deposit Account 13-1130.

Respectfully submitted,



Loren Donald Pearson, Reg. No. 42,987  
Dale Paul DiMaggio, Reg. No. 31,823  
Malin, Haley, DiMaggio & Crosby, P.A.  
One East Broward Blvd., Suite 1609  
Fort Lauderdale, Florida 33301  
(954) 763-3303

2. (Canceled) Please cancel claim 2 without prejudice.

<sup>2</sup>  
a<sup>2</sup> 3. (Once Amended) The test strip of claim [2] 1, wherein said dam partitions are oriented around said receiving port.

NEWLY ADDED CLAIMS

sub B1 > -- ~~422~~. (Added) A diagnostic sanitary test strip device for measuring an analyte of interest in a heterogenous fluid sample, said test strip comprising:

(a) an upper support layer defining a sample receiving port for receiving the fluid sample therein;

(b) means for retaining the fluid sample to prevent spillage of the sample from said strip to make said test strip sanitary;

(c) means, in vertical alignment and contiguous contact with said sample receiving port, for uniformly spreading the fluid sample in said receiving port before allowing said fluid sample to vertically pass through said spreading means;

(d) means, in contiguous contact with said spreading means, for filtering the fluid sample received from said spreading means to remove at least one undesirable element in the fluid sample prior to passing the fluid sample through said filtering means;

(e) a reaction membrane, in contiguous contact with said filtering means, having a predetermined porosity, said membrane retaining a reagent solution capable of reacting with the analyte

of interest to produce a color change in said membrane corresponding to the amount of analyte present in the fluid sample;

(f) a lower support layer in contiguous contact with said membrane and having a reaction viewing port in vertical alignment with said membrane for displaying said color change, wherein said retaining means, said spreading means, said filtering means, and said reaction membrane interpose said lower support and said upper support to secure said test strip; and

(g) a means for properly orienting said test strip in a corresponding meter.--

<sup>22</sup> ~~43~~ <sup>21</sup> 23. (Added) The test strip of claim ~~42~~, wherein said orienting means comprises a light absorption medium on an exposed surface of said upper layer.--

<sup>23</sup> ~~44~~ 24. (Added) A diagnostic sanitary test strip device for measuring an analyte of interest in a heterogenous fluid sample, said test strip comprising:

(a) an upper support layer defining a sample receiving port for receiving the fluid sample therein and a plurality of detents for mating with securing posts in a corresponding reflectance meter;

(b) means for retaining the fluid sample to prevent spillage of the sample from said strip to make said test strip sanitary;

(c) means, in vertical alignment and contiguous contact with said sample receiving port, for uniformly spreading the fluid sample in said receiving port before allowing said fluid sample to vertically pass through said spreading means;

(d) means, in contiguous contact with said spreading means, for filtering the fluid sample received from said spreading means to remove at least one undesirable element in the fluid sample prior to passing the fluid sample through said filtering means;

*3*  
*cancel*  
(e) a reaction membrane, in contiguous contact with said filtering means, having a predetermined porosity, said membrane retaining a reagent solution capable of reacting with the analyte of interest to produce a color change in said membrane corresponding to the amount of analyte present in the fluid sample; and

(f) a lower support layer in contiguous contact with said membrane and having a reaction viewing port in vertical alignment with said membrane for displaying said color change, wherein said retaining means, said spreading means, said filtering means, and said reaction membrane interpose said lower support and said upper support to secure said test strip.--